

REMARKS

This application has been carefully reviewed in light of the outstanding Office Action. Claims 2-17, 19 and 21-42 remain in this application, of which Claims 4-12, 15, 17 and 21-32 have been withdrawn from examination as being directed to non-elected species. Claims 2, 19 and 33 have been amended to define still more clearly what Applicant regards as his invention, in terms that distinguish over the art. Claim 43 has been added to assure Applicant of a full measure of protection. Of the claims under consideration, Claims 2, 13, 19 and 33 are independent.

Independent Claim 2, directed to an individual implant, now specifies that the implant is one of a list of types of such implants that are used in rhinoplasty. More particularly, Claim 2 now states explicitly that the implant is “a rhinoplastic augment having an augmenting surface shaped to impart a predetermined desirable shape to external tissue of the patient from a position at which the augment is implanted within the patient”.

The Office Action appears to consider merely “functional” and not structure, the recitation in Claim 2 that the claimed object is shaped to impart a predetermined desired shape to a patient’s skin upon implantation. To clarify that the shape that is imparted to the patient’s face is the result of the skin and layers of underlying tissue resting on, and thus being shaped by, the implant, the recitation has been reworded to state that the object is “*shaped to serve as a rhinoplastic augment, having an augmenting surface having a predetermined shape* to be imparted to external tissue of the patient from a position at which the augment is implanted within the patient [emphases added]”. Applicant submits that this recitation is not merely functional, but defines structure, specifically, the shape, of the surface in question.

As was pointed out in Applicant’s last Amendment, nothing in *Bolanos* appears to have such a shape. The statement in the outstanding Office Action that “the prior art device is capable of performing the broadly claimed function” is noted, but is

believed to be incorrect. Applicant understands the Examiner's view that the recitation in question merely stated an intended use of the claimed object, or at the most, was a functional recitation devoid of structural significance, but believes that the Examiner's view is only partially correct. While it is certainly true that the intended use of the claimed object is as a rhinoplastic implant, which has "an augmenting surface having a predetermined shape to be imparted to external tissue of the patient from a position at which the augment is implanted within the patient", it is believed to be common knowledge that rhinoplasty is a procedure directed to improving the appearance of the patient's nose. Even granting a good deal of variation from one person to another as to what shape in a nose is attractive, this circumstance imposes fairly tight constraints on the shapes that it might be desired to impart to the patient's nose in such a procedure. If the Examiner's comment is based on the idea that pretty much any object if implanted will result in the imparting of some shape to the patient's body, therefore, that idea is believed to be misplaced with regard to Claim 2.

That is, the implant claimed in Claim 2 has a surface whose form the surgeon will use to give a desired shape to the patient's nose, and in fact the shape of the augment itself is what serves this purpose. Applicant submits that nothing found or pointed out in *Bolanos* has a shape as recited in Claim 2.

Moreover, Claim 2 also recites that the augment is "one of a button, a dorsal augment, a unilateral tip, a bilateral tip, a pair of tips with a Y-connector joined to the tips, a nasal vault reconstruction module, a heart-shaped augment, a septal perforation module and a mesh element". Applicant submits that nothing has been found, or pointed out, in *Bolanos* that would teach or suggest any of these structures. Accordingly, it is believed clear that Claim 2 is certainly not anticipated by *Bolanos*.

Further, it is not seen why one of merely ordinary skill would have considered making or using a structure as claimed in Claim 2, based on anything in *Bolanos*.

For all these reasons, it is believed that Claim 2 is allowable over *Bolanos*.

Independent Claim 19, directed to a kit, has been amended by specifying that the elements in the kit include at least one strut, and at least one rhinoplastic augment selected from a list of types. Claim 19 now recites that at least one object in the kit is a rhinoplastic augment, and the language added to Claim 2 about the augment has been added to Claim 19 as well.

In addition, however, Claim 19 recites “a strut that has at least one portion extending in a first direction, said portion having a plurality of through-openings formed in it and arranged adjacent to each other in a row that extends in said first direction, said through-openings being formed such as to increase the ease with which said strut can be bent in at least one direction transverse to said first direction”. From the penultimate Office Action, it appears that the Examiner considers a certain female connector element in *Bolanos* to be such a strut, except in lacking the recited through-openings, and considers that the provision of such through-openings would have been obvious “in order to allow for greater flexibility of placement during nasal procedures”. Applicant understands the female connector element in question to be element 220 shown in Fig. 7 of that patent. (If Applicant’s understanding is incorrect, Applicants requests clarification.) Applicant submits that one of merely ordinary skill would have had no reason to consider making such a modification to what is shown in *Bolanos*. Element 220 is apparently provided merely as a nut to engage with and secure element 210 (note that element 220 is termed a “retainer portion” in *Bolanos*). There is no need seen for retainer element 220 to be flexible in the manner recited in Claim 19 (“said through-openings being formed such as to increase the ease with which said strut can be bent in at least one direction transverse to

said first direction”), and in fact, it appears that such flexibility might very easily interfere with the element’s suitability for its intended purpose. At the very least, however, no reason is seen why one of ordinary skill would consider making such a modification, either for the sake of flexibility or for any other purpose.

For all these reasons, therefore, Claim 19 is also believed to be allowable over *Bolanos*.

Independent Claim 33, also directed to a kit, again specifies that the kit includes a strut and at least one augment from a list of known types of rhinoplastic augments. Again, the language added to Claim 2 has also been added to this claim. The claim differs from the other independent claims under consideration in not specifying that the connectors provided on the at least two elements are male and female ones that are attachable to each other by means of a snapping engagement, but merely are securable to each other without the use of screws. The claim also specifies that the two elements, as provided in the kit, are not in engagement with each other. (This, for one thing, distinguishes the claimed kit from a surgical implant in which the manufacturer has used a snap-fit to join two pieces of the device, as in *Tallarida*.) Accordingly, Claim 33 also is deemed allowable over the art cited against it, for all the reasons that apply to Claim 19.

Independent Claim 13 is directed to an individual strut, having the structure quoted above from Claim 19 relating to the strut that forms part of the kit of Claim 19. Moreover, Claim 13 also recites that the strut has either a male or a female connector element, the “female connector element comprising material *extending from said strut* and defining a receptacle, and said male connector element comprising material having a shape and size to be received snappingly in such receptacle [emphasis added]”. Applicant notes the statement in the outstanding Office Action that Applicant’s previous argument relating to this claim and *Bolanos* “amount to a mere allegation of patentability and non-obviousness”. Applicant’s previous point, which is reiterated, is that Applicant has been

unable to identify what structure in *Bolanos* could properly be viewed as a “female connector element comprising material *extending from said strut* and defining a receptacle [emphasis added]”, or a “male connector element comprising material having a shape and size to be received snappingly in such receptacle”. Assuming that retainer element 220 is a “strut”, no material extending therefrom as part of a female connector is seen, nor has any been identified in any of the previous Office Action, as far as Applicant is able to find. Thus, Applicant did not mean to present only a bare allegation of patentability and non-obviousness, but believed that the outstanding rejection was (and remains) deficient even as a *prima facie* case of obviousness, as not all the elements of the claim have been identified in the reference, or alleged by the Office to be merely obvious variations from a structure taught by such reference.¹

Accordingly, it is believed that Claim 13 is allowable over *Bolanos*, even if it be assumed for argument’s sake that the addition of through-holes would have been obvious.

In fact, however, it is not seen how through-holes could be provided in an element of the thickness of element 220 in such manner as to make the element easier to bend, as is recited in Claim 13, nor is any other reason to add such holes seen to exist. Accordingly, Applicant cannot agree that the proposed modification would have been obvious to one of merely ordinary skill.

^{1/} It is believed that this point was made clearly in Applicant’s last Amendment: “After careful study of the prior art, Applicant does not see what in *Bolanos* would meet the recitations “said female connector element comprising material *extending from said strut* and defining a receptacle, and said male connector element comprising material having a shape and size to be received snappingly in *said receptacle* [emphases added]”. Assuming that element 220 in Fig. 7 of that patent is deemed a strut, nothing in that patent suggests the quoted recitation; rather, the mere shape of aperture 221 defines the female connector. Since the recited material extending from a strut and defining a receptacle is not met by *Bolanos*, nothing in that patent could suggest a male element shaped and sized to fit snappingly in that receptacle.”

On both grounds, therefore, Claim 13 is believed to be clearly allowable over *Bolanos*.

A review of the other art of record has failed to reveal anything which, in Applicant's opinion, would remedy the deficiencies of the art discussed above, as a reference against the independent claims under consideration herein. Those claims are therefore believed patentable over the art of record.

The other claims under rejection in this application are each dependent from one or another of the independent claims discussed above and are therefore believed patentable for the same reasons. Since each dependent claim is also deemed to define an additional aspect of the invention, however, the individual reconsideration of the patentability of each on its own merits is respectfully requested.

Applicant respectfully requests favorable reconsideration and early passage to issue of the present application.

Applicant's undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

/Leonard P Diana/
Leonard P. Diana
Attorney for Applicant
Registration No. 29,296

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200